UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

RANDALL HIX, *et al.,*

Plaintiffs,

v.

ZIMMER BIOMET HOLDINGS, INC, *et al*.,

Defendants.

Case No. 3:18-cv-00437-RCJ-WGC

ORDER

In 2010, Randall Hix had an artificial hip replacement using a Biomet M2a Magnum implant. Hix and his wife, Liana Hix, brought this suit against Defendants Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC, (collectively "Biomet") alleging the artificial hip device was defective. (Amended Complaint, ECF No. 201). Presently before the Court is Hix's motion to exclude the pain-causation opinions and testimony of Dr. Edgar L. Ross, one of Biomet's case-specific experts (ECF No. 275). Biomet opposes the motion. (ECF No. 283). Having considered the arguments and the supporting record, the Court will deny the motion.

I. PROCEDURAL HISTORY

On October 2, 2012, the Judicial Panel on Multidistrict Litigation transferred the first actions regarding Biomet M2a Magnum hip implants to the Northern District of Indiana as the Biomet M2a Magnum Hip Implants Products Liability multi-district litigation, MDL Case No. 3-12-md-2391. In February 2013, the MDL court entered an order allowing parties to file new actions directly into the

MDL action. In March 2014, Hix initiated this action by filing a complaint in the Biomet M2a Magnum MDL. Following consolidated pre-trial proceedings primarily directed to common-issue discovery and to some case-specific discovery, the MDL court transferred this matter to the District of Nevada in September 2018.

II. BACKGROUND

On July 12, 2010, Hix (then 36 years old) had a total hip arthroplasty (THA, i.e., joint replacement) performed by Dr. Richard Mullins. Dr. Mullins implanted the Biomet M2a Magnum metal-on-metal (MoM) artificial hip device.

Prior to the THA procedure, Hix had surgery in 1997 on his left hip due to a Slipped Capital Femoral Epiphysis when he was 13 years old.

In 2008, Hix began experiencing pain in his left hip that worsened over time. In March 2010, Hix was arthroscopically treated for left hip femoroacetabular impingement. When the procedure did not resolve Hix's pain, he was referred to Dr. Mullins, who recommended a total left hip replacement. Hix and Dr. Mullins met with a Biomet sales representative who demonstrated Biomet's sample hip prosthetics. Dr. Mullins thought that a metal-on-metal device would provide Hix a better quality of life – and would last longer – than a metal-on-polyethylene device. Hix decided to have the M2a Magnum MoM device implanted.

Following the THA procedure, Hix began again experiencing pain in his left hip in March 2012. He saw Dr. Suzanne Zsikla, who referred Hix to Dr. Richard Blakey, an orthopedic surgeon. Hix saw Dr. Blakey in August 2012. A radiograph was taken, showing the MoM implant with reactive bone at the end of the stem. A presumptive diagnosis of metallosis[1] was made.

[1] In his deposition, Hix's treating physician, Dr. Blakey, described metallosis as an inflammatory reaction to the wear product of an MoM device.

A bone scan performed on September 5, 2012, indicated Hix's hip was normal and did not indicate an abnormal uptake. On September 11, 2012, Dr. Blakey indicated he was fairly certain Hix did not have an infection and recommended a revision of the Biomet M2a Magnum MoM hip device.

Dr. Blakey performed the revision surgery on Hix's left hip on October 31, 2012. Dr. Blakey removed the Biomet acetabular cup and replaced it with a Zimmer metal-on-polyethylene constrained hip construct. He also removed damaged tissue and implanted a constrained liner to reduce the chance of dislocation or subluxation. Dr. Tony Yang examined the removed tissues for pathology and noted chronic inflammation, reactive hyperplasia, and pigmented macrophages containing a grayish pigment consistent with foreign material. Dr. Blakey's post-operative diagnosis noted painful left metal-on-metal total hip secondary to metallosis.

Two weeks after this surgery, Hix had an MRI of his lumbar spine, which showed an L5-S1 right-sided paracentral disc protrusion causing mild stenosis of the right neural foramina.

On January 10, 2013, Hix was seen by Dr. Blakey as Hix had "developed some cellulitis about the left hip wound." Dr. Blakey informed Hix that he might need to aspirate the hip. This procedure was performed on January 24, but produced "little fluid, if any." Cultures on the fluid were negative for infection. Hix was continuing to have pain when he had an office visit with Dr. Blakey in June 2013. Dr. Blakey "talked to [Hix] about the fact that sometimes the metallosis reaction comes back even though we have revised the hip." Dr. Blakey performed another left-hip aspiration in August 2013 and gave Hix a steroid injection.

Hix had a follow-up visit a week later. Dr. Blakey recorded in his notes: "I suspect that he is having continued inflammation, possibly from the metallosis." Following an office visit two weeks later, Dr. Blakey noted there was not much else he could do for Hix's pain.

Hix continued to have pain through 2014. In November 2014, Hix saw Dr. Martin Arraiz, who noted radiculitis (pain radiating along a nerve resulting from inflammation at the root of the nerve connecting to the spine) in the lower left extremity. Hix received an epidural injection in December 2014.

Hix saw Dr. Blakey in January 2015. Dr. Blakey noted Hix "is actually getting better with respect to his left hip. He is still having pain." Following a July 2015 office visit, Dr. Blakey noted "Hix has had increasing pain in his left hip revision last month."

On October 21, 2017, Hix went to the emergency room the day following "kicking an object . . . with his left leg" that resulted in "sudden onset pain left hip." The emergency doctor noted a final impression of "[p]ain of left hip joint" and "[d]islocation of left hip."

Two days later, Dr. Chad Watts performed a revision surgery on Hix's left hip for "failed constrained liner with dislocation of left total hip." Dr. Watts removed the cup with constrained liner and replaced it with a "62 Biomet OsseoTi shell with dual mobility liner" and "2B +6 revision ceramic head with a titanium sleeve." Dr. Watts notes indicate that Hix "was very scarred in and had a pretty stiff hip. There was some metal staining from his prior metallosis, but overall the muscle and tissues were in reasonable shape." He further noted the "constrained liner was broken – there had clearly been chronic impingement which led to failure."

Four weeks after the surgery, Hix visited the emergency room with "pain to the surgical site, redness, and drainage around surgical incision associated with fever (102.0 deg F) and chills." Hix underwent surgery the following day to open the surgical wound for "drainage with debridement and placement of wound VAC." Two days later, Dr. Robert Crouse performed another surgery. As Hix had "an obvious deep infection," Dr. Crouse removed the artificial hip devices, removed infected material for biopsy and culture, and performed a femoral osteotomy. Dr. Crouse further placed an antibiotic impregnated cement spacer in the acetabulum, the location of the infection. The material

removed for culture showed growth for Staphylococcus lugdunensis, with 1 of 3 cultures showing growth for Methicillin-Resistant Staphylococcus aureus. Hix remained on IV antibiotics for six weeks.

On February 8, 2018, Dr. Watts implanted an artificial hip consisting of a Stryker Restoration cup and stem with a ceramic head and cable.

Hix had an office visit with Dr. Ali Nairizi in June 2018 for pain management. Over the following year, Hix underwent a femoral nerve block, lumbar sympathetic nerve block, and SI joint injections with corticosteroids for pain.

In September 2019, Dr. Denis Patterson implanted a temporary dorsal root ganglion spinal cord stimulator for pain management and implanted a permanent stimulator the next month.

In November, Hix had an office visit with Dr. Watts, reporting a significant increase in pain and redness and swelling around the left hip. Dr. Watts recorded the impression of "[l]ikely infected left hip replacement." Dr. Watts aspirated the left hip. A culture of the withdrawn material indicated a streptococcus viridans infection. Hix underwent surgery on his left hip the following day, with Dr. Watts performing a tissue debridement and irrigation, and exchanging the MDM liner, the ceramic head and MDM head. On December 1, 2019, Dr. Watts performed another debridement and irrigation of the hip. Hix was hospitalized for the infected left hip from November 22, through December 11, 2019.

In May 2020, Dr. Patterson exchanged the implantable power generator for the nerve stimulator.

III. LEGAL STANDARDS

A. Admissibility of Expert Testimony

Federal Rule of Evidence 702 governs the admission of expert testimony and provides that if a witness is qualified as an expert by knowledge, skill, experience, training, or education, the witness can provide opinion testimony so long as:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The task of the trial court is to "assure that the expert testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" *Primiano v. Cook,* 598 F.3d 558, 564 (9th Cir. 2010) *quoting Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 597 (1993). This task applies to all expert testimony governed by Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-148 (1999). Rule 702 "is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of [the relevant] discipline." *Daubert*, 509 U.S. at 592. The party offering the expert witness "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 Advisory Committee Notes.

"[M]any factors will bear on the inquiry." *Daubert*, 509 U.S. at 593. In considering the admissibility of scientific expert testimony, the Supreme Court generally noted four factors while acknowledging that it was not setting "out a definitive checklist or test." *Id.* As summarized by the Ninth Circuit, a court may consider: "1) whether the theory can be or has been tested; (2) whether

the theory has been subjected to peer review and publication; (3) the known or potential rate of error and the existence of standards controlling a technique's operation; and (4) whether or not the theory is generally accepted." *United States v.Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). However, these factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho*, 526 U.S. at 150. Ultimately, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

IV. DISCUSSION

Dr. Ross offers three discrete opinions in his Report: (1) Mr. Hix's long-term pain was not solely related to his left hip, and the pain he presently complains of would exist even if he had never had a hip replacement and associated revisions; (2) Mr. Hix's prolonged use of high-dose opioids predated his left-hip replacement, and contributes to his ongoing, altered perception of pain; and (3) Mr. Hix's long term prognosis for pain relief was poor, due to his history of chronic pain and reliance on high doses of pain medication. Dr. Ross offers two additional opinions in his rebuttal report: (1) Mr. Hix's chronic pain would have the same clinical presentation—lower back pain, hip pain, and opioid hyperalgesia—even if he had a healthy, natural hip; and (2) the effectiveness of treatment Mr. Hix sought for his back and the ineffectiveness of treatment sought for his left hip jointly suggest that Mr. Hix's pain originates in his back.

Hix seeks to exclude Dr. Ross's opinions that his chronic pain would "exist even without his left hip replacement and revisions" and that his "clinical [pain] presentation would have been the same regardless of the orthopedic condition of his left hip." He argues these opinions are not supported by the medical records and testimony, as Dr. Ross fails to give due consideration to the metallosis, which Hix argues is the primary causal source of Hix's pain. That is, Hix argues that Dr.

Ross did not perform a proper differential diagnosis that took serious account of the potential cause of Hix's pain that Hix believes is primary cause of that pain. Hix notes that, other than quoting Dr. Shapiro's reference metallosis, Dr. Ross never uses the word metallosis in his reports, nor does he discuss metallosis relative to Hix's pain.

Biomet responds that Dr. Ross's opinions are appropriate as they "provide the perspective of a pain-management physician on the various etiologies of Mr. Hix's chronic pain *outside of* his left hip replacement and subsequent revisions." Biomet further asserts that Dr. Ross focuses his analysis on identifying the etiology of Mr. Hix's various chronic pain complaints consistent with what his knowledge, experience, and the body of literature in his field support."

Whether Dr. Ross should be permitted to testify regarding the two specific opinions targeted by Hix – (1) that Hix's chronic pain would "exist even without his left hip replacement and revisions" and that his "clinical [pain] presentation would have been the same regardless of the orthopedic condition of his left hip" – presents a difficult question. The opinions, as stated by Dr. Ross in his reports, appear to be inconsistent with Biomet's arguments as to the substance of those opinions. For example, Biomet argues that Dr. Ross's opinion is that "*some* of the pain Mr. Hix complains of today has an alternative cause." As written by Dr. Ross, however, his opinion appears to suggest that he does not attribute any of the pain Hix has suffered and continues to suffer to orthopedic condition of Hix's left hip, suggesting he would have suffered the same hip pain "even with a healthy, natural hip."

Nevertheless, the Court will not exclude these specific opinions by Dr. Ross's opinions at this time. *Daubert* requires only that an expert's opinion has "a reliable basis in the knowledge and experience of [the relevant] discipline," *Daubert*, 509 U.S. at 592, not an unassailable basis for that opinion. Given Hix's examination of Dr. Ross in deposition, the Court finds the issues identified by Hix, while they appear to be substantial, do not rise to the level of precluding Dr. Ross from testifying

as to these opinions. Rather, the issues raised by Hix are better directed to the weight to be given to the opinions, rather than the admissibility of those opinions. As Hix did at Dr. Ross's deposition, he may present these issues to the jury through the cross-examination process.

CONCLUSION

IT IS HEREBY ORDERED that the Partial Motion in Limine to Exclude the Opinions and Testimony of Dr. Edgar L. Ross brought by Randall Hix and Liana Hix (ECF No. 275) is DENIED.

IT IS SO ORDERED.

Dated: March 29, 2022

ROBERT C. JONES
United States District Judge